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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,385	09/05/2003	Pragnya J. Desai	JJPR-0036	9589

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,385	DESAI ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a method of identifying compounds that modulate mammalian histamine H4 receptor activity, said compound being ***either*** an inhibitor, an activator, an antagonist, an agonist ***or*** an inverse agonist, said method comprising measuring the effect of the compound on protein function or ability to bind the ligand by combining a test compound with a mammalian histamine H4 receptor and a known histamine receptor H4 ligand, classified in Class 435, subclass 7.1.

Note Absent evidence to the contrary, each of the recited methods is distinct since the activity and mode of modulation of each compound is not obvious over the other activity and mode of modulation, *i.e.,* each compound binds a different set of ligand(s) and modulates in a different way a different component of mammalian histamine H4 receptor activity. Therefore the instant claims 1-6 encompass hundreds of GROUPS, not species.

For example, Applicant might elect the said method wherein the modulation is inhibition of mast cell chemotaxis and the compound competes for and inhibits binding binding of histamine to the human histamine H4 receptor. For example, Applicant might elect the said method wherein the modulation is inhibition of basophil chemotaxis via antagonist activity of the mammalian histamine H4 receptor second messenger calcium.

II. Claims 7-9, 12, 14, 16 and 18-23, drawn to a compound and pharmaceutical composition thereof, comprising ***either*** an inhibitor, an activator, an antagonist, an agonist ***or*** an inverse agonist of a mammalian histamine H4 receptor, classified in Class 536, subclass 6.2 and Class 514, subclass 740.

Note Absent evidence to the contrary, each of the recited compounds is distinct since each ligand(s) to which each of said protein antigens/functional derivatives thereof is specific for is not obvious over the other set of ligand(s) and each modulates a specific activity and in a specific mode. Therefore the instant claims 7-9, 12, 14 and 16-23 encompass hundreds of GROUPS, not species.

For example, Applicant might elect the said compound/composition thereof wherein the modulation exhibited by said compound is inhibition of mast cell chemotaxis activity and the compound competes for and inhibits binding of histamine to the human histamine H4 receptor, said compound being a small organic molecule. For example, Applicant might elect the said compound/composition thereof wherein the modulation exhibited by said compound is inhibition of basophil chemotaxis via antagonist activity of the mammalian histamine H4 receptor second messenger calcium, said compound being a small organic molecule.

III. Claims 10 and 11, drawn to a monospecific antibody that reacts with a mammalian histamine H4 receptor protein, wherein said antibody ***either*** blocks histamine binding ***or*** activation of the mammalian histamine H4 receptor protein, and wherein the antibody ***either*** modulates mast cell chemotaxis ***or*** basophil chemotaxis, classified in Class 530, subclass 388.1.

Note Absent evidence to the contrary, each of the recited antibodies is distinct since each ligand(s) to which each of said antibodies is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 10 and 11 encompass hundreds of GROUPS, not species.

For example, Applicant might elect an antibody specific the human histamine H4 receptor protein said antibody inhibits mast cell chemotaxis activity and inhibits binding of histamine to the human histamine H4 receptor. Or Applicant might elect the said antibody that inhibits basophil chemotaxis via binding to a second messenger.

IV. Claims 13, 15, 17 and 24-29, drawn to a method for modulating asthma or an allergic response or a disease or condition mediated by one or the other, said method comprising administration of a pharmaceutical composition comprising a compound that is ***either*** an inhibitor, an activator, an antagonist, an agonist ***or*** an inverse agonist of a mammalian histamine H4 receptor, classified in Class 514, subclass 740.

Note Absent evidence to the contrary, each of the recited compounds is distinct since each ligand(s) to which each of said compounds thereof is specific for is not obvious over the other set of ligand(s) and each modulates a specific activity and in a specific mode. Therefore the instant claims 13, 17 and 24-29 encompass hundreds of GROUPS, not species.

For example, Applicant might elect the said method wherein the compound in the pharmaceutical composition modulation inhibits mast cell chemotaxis activity and the compound competes for binding and inhibits binding of histamine to the human histamine H4 receptor, said compound being a small organic molecule. Or Applicant might elect the said method wherein the compound in the pharmaceutical composition inhibits basophil chemotaxis via antagonist activity of the mammalian histamine H4 receptor second messenger calcium, said compound being a small organic molecule.

V. Claim 30, drawn to a method of identifying compounds that modulate mammalian histamine H4 receptor activity, said compound being ***either*** an inhibitor, an activator, an antagonist, an agonist ***or*** an inverse agonist, and said method comprising measuring mast cell migration or number in response to placing mast cells in proximity to histamine in the presence or absence of a test compound, classified in Class 435, subclass 7.1.

Note Absent evidence to the contrary, each of the recited methods is distinct since the activity and mode of modulation of each compound is not obvious over the other activity and mode of modulation, *i.e.,* each compound binds a different set of ligand(s) and modulates in a different way a different component of mammalian histamine H4 receptor activity. Therefore the instant claim 30 encompasses hundreds of GROUPS, not species.

For example, Applicant might elect the said method wherein the modulation is inhibition of mast cell chemotaxis activity and the compound competes for binding and inhibits binding of histamine to the human histamine H4 receptor, the compound being a small organic molecule.

VI. Claim 31, drawn to a method of determining if a histamine H4 receptor modulating compound modulates sub-epithelial accumulation of mast cells in a mammalian trachea in response to exposure to histamine or an allergen, said compound being ***either*** an inhibitor, an activator, an antagonist, an agonist ***or*** an inverse agonist, and said method comprising measuring sub-epithelial mast cell accumulation in said trachea in the presence or absence of the compound in response to placing mast cells in proximity to histamine in the presence or absence of the said compound by exposing a mammal to an aerosol comprising histamine or an allergen, classified in Class 435, subclass 7.2.

Note Absent evidence to the contrary, each of the recited methods is distinct since the activity and mode of modulation of each compound is not obvious over the other activity and mode of modulation, *i.e.,* each compound binds a different set of ligand(s) and modulates in a different way a different component of mammalian histamine H4 receptor activity. Therefore the instant claim 31 encompasses hundreds of GROUPS, not species.

For example, Applicant might elect the said method wherein the modulation is inhibition of mast cell chemotactic activity and the compound competes for binding and inhibits binding of histamine to the human histamine H4 receptor.

2. The GROUPS encompassed by Inventions II and III are directed to related inventions. The related inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.,* are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the compound of the Groups encompassed by Invention II may be a small organic molecule or other compound that is not immunologically reactive with a mammalian histamine H4 receptor protein, whereas the antibody of the Groups encompassed by Invention III is comprised of amino acid residues and is immunologically reactive with a mammalian histamine H4 receptor protein.

3. The GROUPS encompassed by Inventions I, IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are different methods with different ingredients, method steps and endpoints. For example, the GROUPS encompassed by Inventions I and V are methods of identifying compounds that modulate mammalian histamine H4 receptor activity by measuring *in vitro* the effect of the compound on protein function or ability to bind a ligand (I) or by measuring *in vitro* the migration of mast cells (V), whereas the GROUPS encompassed by Invention IV are *in vivo* methods of treatment, whereas the GROUPS encompassed by Invention VI are *in vivo* methods of determining if a compound modulates sub-epithelia accumulation of mast cells in the human trachea in response to histamine or an allergen.

4. The GROUPS encompassed by Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as detection assays.

5. The GROUPS encompassed by Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as detection assays.

Therefore they are patentably distinct.

6. Because these inventions are distinct for the reasons given above and the search required for any GROUP encompassed by I-VI is not required for any other GROUP encompassed by I-VI, and I-VI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

7. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. **If Applicant elects one of the GROUPS encompassed by Inventions II *OR* IV,** Applicant is further required to (1) elect a single disclosed species (***a specific compound or a specific compound (III) to be used in the claimed method (IV)***, for example, Imetit) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

9. **If Applicant elects one of the GROUPS encompassed by Invention III,** Applicant is further required to (1) elect a single disclosed species of antibody (***a specific antibody that blocks a specific activity,*** for example, the antibody blocks activation of the mammalian histamine H4 receptor by binding to the receptor) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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